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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/375,514	08/17/1999	JOHN C. REED	3335-075-55-	5198

7590 07/15/2003

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EXAMINER
SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
1635	27

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/375,514	REED, JOHN C.	
	Examiner	Art Unit	
	Mary M. Schmidt	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53 and 70-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *53 and 76-81* is/are allowed.

6)☒ Claim(s) *70-73,75 and 82-88* is/are rejected.

7)☒ Claim(s) *74* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 August 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 70 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,414,134. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 70 is drawn to an anticode oligomer, wherein said anticode oligomer is from 10 to 40 bases in length and is complementary to a portion of SEQ ID NO:19.

Claim 1 of '134 is drawn to an antisense oligonucleotide of 17 to 35 bases in length, wherein said antisense oligonucleotide is complementary to bcl-2 mRNA, and wherein said antisense oligonucleotide comprises the nucleotide sequence of SEQ ID NO:9.

SEQ ID NO:9 in '134 has the same sequence as SEQ ID NO:9 in the instant specification, which is the complementary sequence of instant SEQ ID NO:19, starting at the start ATG (see page 13, lines 3 and 4 of the instant specification and instant SEQ ID NO:9). Thus, claim 1 of '134 anticipates instant claim 70 since it taught an anticode oligomer from 10-40 bases in length that is complementary to a portion of SEQ ID NO:19, specifically the start site region of SEQ ID NO:19.

3.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 71, 73, 75 and 82-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 is drawn to an anticode oligomer, wherein said anticode oligomer is from 10 to 40 bases in length and is complementary to a portion of SEQ ID NO:22. SEQ ID NO:22 is an amino acid sequence and not a nucleic acid sequence. Traditionally, an oligomer refers to a nucleic acid sequence and thus it is not clear what type of sequence is to bind to the amino acid sequence of SEQ ID NO:22, an amino acid sequence or a nucleic acid sequence. Page 8 of the specification as filed, lines 14-20, define "anticode oligomers" as "chemical species that recognize polynucleotide target sequences through hydrogen bonding interactions with the nucleotide bases of the target sequences. The target sequences may be single- or double-stranded RNA or single- or double-stranded DNA." Thus, the claims are indefinite since the claimed target is a protein, amino acid, sequence and the anticode oligomers are not defined in the specification as able to bind a protein, but rather as defined by hydrogen bonding to a nucleic acid sequence.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP 2163 teaches the following conditions for the analysis of the claimed invention at the time the invention was made in view of the teachings of the specification and level of skill in the art at the time the invention was made:

> The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence....A lack of written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process....Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement....The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Claim 72 lacks written description for a representative number of species of the claimed antisense to a splice acceptor region of SEQ ID NO:19. The specification as filed only teaches on page 13 the sequence of one splice acceptor region. The specification as filed thus does not provide an adequate description of other possible splice acceptor regions. Absent further specific guidance as to other regions considered splice acceptor regions, one of skill in the art would not have recognized that applicant was in possession of a representative number of species of the genus of antisense claimed to any such region.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 70 is rejected under 35 U.S.C. 102(e) as being anticipated by Capaccioli et al. (U.S. Patent 6,005,095).

Claim 70 is drawn to an anticode oligomer, wherein said anticode oligomer is from 10 to 40 bases in length and is complementary to a portion of SEQ ID NO:19.

Capaccioli et al. taught a 30 base nucleic acid, SEQ ID NO:24, where bases 3-30 of SEQ ID NO:24, are complementary to bases 4504-4531 of instant SEQ ID NO:19.

Capaccioli et al. thus met the structural limitations of instant claim 70 since they taught a nucleic acid construct within the range of 10-40 nucleic acids that is complementary to a portion of SEQ ID NO:19, specifically bases 4504-4531.

9. Claim 70 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/27663.

Claim 70 is drawn to an anticode oligomer, wherein said anticode oligomer is from 10 to 40 bases in length and is complementary to a portion of SEQ ID NO:19.

WO 96/27663 taught a 30 base nucleic acid where bases 3-30 of the nucleic acid are complementary to bases 4504-4531 of instant SEQ ID NO:19. (Although they do not specify the nucleic acid by SEQ ID NO., it is the same bcl-2, 3' UTR, PCR primer sequence found in U.S. Patent 6,005,095, as SEQ ID NO:24)

WO 96/27663 thus met the structural limitations of instant claim 70 since they taught a nucleic acid construct within the range of 10-40 nucleic acids that is complementary to a portion of SEQ ID NO:19, specifically bases 4504-4531.

Allowable Subject Matter

10. Claim 74 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 53 and 76-81 are allowed.

12. Claims 53 and 71-88 are considered free of the prior art since (1) claims 71, 73, 75 and 82-88 as dependent on claim 71, were not definite as set forth in the 35 U.S.C. 112, second

paragraph, rejection above; (2) claims 53 and 76-81 are free of the prior art for SEQ ID NO:17; (3) claims 72, 74, and 75, 82-88 as they are dependent on claims 72 and 74, are free of the prior art since the prior art did not teach nor fairly suggest antisense to the 5' UTR and splice donor sites of SEQ ID NO:19, nor the claimed modifications (phosphorothioate or phosphoramidate), of the PCR primers to the 3' UTR of bcl-2 as taught by Capaccioli et al. (U.S. Patent 6,005,095 and WO 96/27663) set forth above. Furthermore, claim 75 as dependent on claim 70 is considered free of the prior art since the instant specification states on page 14, lines 16-25, that "pharmaceutical carrier" refers to a composition such as a cationic lipid or liposome, which is different from a "physiologically acceptable carrier or diluent, such as a saline solution or other suitable liquid." While Capaccioli et al. (U.S. Patent 6,005,095 and WO 96/27663) taught motivation for use of their SEQ ID NO:24 primer in amplification reactions (which have a liquid buffer), they did not provide motivation to enclose the primer sequence SEQ ID NO:24 in a liposomal type composition.

13. Please note that priority in the instant application for SEQ ID NOS. 19 and 22 is given only to the filing date of the instant application 09/375,514, of August 17, 1999, since the parent applications, 07/840,716 and 07/288,692, only had 16 nucleic acid sequences, and did not disclose instant SEQ ID NOS. 19 and 22.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Inquiries relating to the status of this application may also be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.

JOHN L. LeGUYADER
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M. M. Schmidt
July 2, 2003